K002068

FEB - 8 2001

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
2601 Campus Drive
Irvine, California 92612-1601
Phone: (800) 325-0283

The device has been classified as Class III by the Cardiovascular Device Classification Panel under 21 CFR Part 870.1025 "Detector and Alarm, Arrhythmia " per DSI and as Class II under 21 CFR 870.2910 "Transmitters and Receivers, Physiological Signal, Radiofrequency" per DRG.

Common names for the device include Signal Exchanger and Telemetry Receiver.

The predicate marketed device is the Nihon Kohden ORG-8200A Multiple Patient Receiver per 510(k) # K912744, commercial distribution certification dated December 9, 1991.

The device is intended for use by medical professionals with Nihon Kohden telemetry transmitters and central stations to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The device will receive and transmit physiological data from telemetry transmitters/receivers and generate an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected.

To date, no special controls or performance standards are known or established for this device.

The device is not sterile.

The device is not contacting. Therefore, no good laboratory practice studies were required per 21 CFR 58.

The device was subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the ORG-9200A Multiple Patient Receiver is substantially equivalent to the Nihon Kohden ORG-8200A Multiple Patient Receiver.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2001

Ms. Bonnie Bishop
Regulatory Affairs Manager
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Re: K002068
Trade Name: Nihon Kohden ORG-9200A Multiple Patient Receiver
Regulatory Class: III (three)
Product Code: DSI
Regulation: 870.1025
Dated: November 9, 2000
Received: November 13, 2000

Dear Ms. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K002068

Device Name: ORG-9200A Multiple Patient Receiver

Indications for Use:

The ORG-9200A Multiple Patient Receiver is intended for use by medical professionals with Nihon Kohden telemetry transmitters and central stations to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The device detects patient vital sign alarm conditions and includes an algorithm to detect cardiac arrhythmias. The device is available for use on all patient populations.

Division of Cardiovascular & Respiratory Devices
510(k) Number K002068